



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,312	02/15/2002	John McKenzie	271/094	3792
30452 7590 04/06/2009 EDWARDS LIFESCIENCES CORPORATION LEGAL DEPARTMENT ONE EDWARDS WAY IRVINE, CA 92614				
EXAMINER				
SWEET, THOMAS				
ART UNIT		PAPER NUMBER		
3774				
MAIL DATE		DELIVERY MODE		
04/06/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/077,312

Applicant(s)

MCKENZIE ET AL.

Examiner

Thomas J. Sweet

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/21/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-10 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Allowable Subject Matter

The indicated allowability of claims 1-3, 6-10 and 12 is withdrawn in view of reference(s) to Bajaj (US 5053008, new interpretation) and Daniel et al (US 5814064, new interpretation) and Engelson et al (US 6066158). Rejections based on the new corrected interpretation reference(s) follow.

Response to Arguments

Applicant's arguments filed 12/01/2005 have been fully considered but they are not persuasive. The priority for the current claims is not properly established in applications 09/016714, 09/467293, 09/387634, 08/993202 and 08/854806, since there are no common inventors.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 1/30/1998, 12/17/1999, 5/12/1997, 12/18/1997 and 8/31/1999 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Applications 09/016714, 09/467293, 08/854806, 09/387634 and 08/993202 does not include the same inventors as the current application and therefore is not eligible as a continuation under 35 USC 120.

35 U.S.C. 120 Benefit of earlier filing date in the United States.

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application.

Interference

Claims 1-3, 6-10 and 12 are rejected under 35 U.S.C. 135(a) based upon claims 1-58 of Patent No. 6254563.

Failure to present claims and/or take necessary steps for interference purposes after notification that interfering subject matter is claimed constitutes a disclaimer of the subject matter. This amounts to a concession that, as a matter of law, the patentee is the first inventor in this country. See *In re Oguie*, 517 F.2d 1382, 186 USPQ 227 (CCPA 1975).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6-10 and 12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, and 8-11 and 17 of U.S. Patent No. 6231544. Although the conflicting claims are not identical, they are not patentably distinct from each other because the obvious combination of claimed subject matter as listed below.

A catheter apparatus for use in a body passage, comprising:

a catheter shaft (claim 1 cannula);

an expandable conduit defined by a filter mesh (claim 1) material of varying porosity (claim 4, establishes a conical shape “umbrella” established on the record by the 132 declaration 12/17/2004 that conical filters inherently have varying porosity) mounted on said catheter shaft (claim 1), said expandable conduit having an upstream end and a downstream end, said expandable conduit having a collapsed position in which said expandable conduit is collapsed toward said catheter shaft and an expanded position in which said upstream end of said expandable conduit is open to fluid flow (claim 1); and

an upstream sealing member at said upstream end of said expandable conduit for creating a seal between said upstream end of said expandable conduit and an internal wall of the body passage (claim 5).

Regarding claim 2, The catheter apparatus of claim 1, wherein said upstream sealing member comprises an inflatable toroidal balloon (claim 11).

Regarding claim 3, The catheter apparatus of claim 1, further comprising a perfusion lumen within said catheter shaft in fluid communication with a space exterior to said expandable conduit (claim 1).

Regarding claim 6, The catheter apparatus of claim 1, further comprising an occlusion member for selectively occluding said expandable conduit (claim 1).

Regarding claim 7, The catheter apparatus of claim 6, further comprising an infusion lumen within said catheter shaft having an infusion port upstream of said occlusion member (claim 10).

Regarding claim 8, The catheter apparatus of claim 7, further comprising a second perfusion lumen within said catheter shaft (claim 10).

Regarding claim 9, The catheter apparatus of claim 1, further comprising a tubular sheath sized to fit over said expandable conduit when in said collapsed position (claim 8).

Regarding claim 10, The catheter apparatus of claim 6, wherein said occlusion member is an inflatable occlusion balloon (claim 17).

Regarding claim 12, The catheter apparatus of claim 1, wherein said catheter shaft is positioned internal to said expandable conduit (claim 1).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-3, 6-10 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsugita et al (6231544) as in the Double Patenting above.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed (it is claimed) in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Claims 1-3, 6-10 and 12 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Tsugita et al (6231544) is patented to the claimed invention and is no a proper parent to this application.

Claims 1-3, 6-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bajaj (5053008). Bajaj discloses a catheter apparatus (fig. 1) for use in a body passage, comprising:

a catheter shaft (16);

an expandable conduit (FIG. 3) defined by a filter mesh (22) material of varying porosity (the mesh is fibers of radial and annular member as seen in fig. 3 which have a tapered hole which get smaller as the mesh gets closer to the catheter 16, additionally members 28 are woven into the mesh also varying the porosity, it is also established on the record by the 132 declaration 12/17/2004 that conical filters fig. 2 inherently have varying porosity) mounted on said catheter shaft (16), said expandable conduit having an upstream end and a downstream end, said expandable conduit having a collapsed position in which said expandable conduit is collapsed toward said catheter shaft and an expanded position in which said upstream end of said expandable conduit is open to fluid flow (as shown in fig. 2); and

an upstream sealing member (20, a balloon) at said upstream end of said expandable conduit for creating a seal between said upstream end of said expandable conduit and an internal wall of the body passage (as shown in fig. 1).

Regarding claim 2. The catheter apparatus of claim 1, wherein said upstream sealing member comprises an inflatable toroidal balloon (20, fig. 3).

Regarding claim 3, The catheter apparatus of claim 1, further comprising a perfusion lumen within said catheter shaft in fluid communication with a space exterior to said expandable conduit (see fig. 1).

Regarding claim 6, The catheter apparatus of claim 1, further comprising an occlusion member for selectively occluding said expandable conduit (the second, filter and balloon upstream shown in fig. 8).

Regarding claim 7, The catheter apparatus of claim 6, further comprising an infusion lumen within said catheter shaft having an infusion port (72) upstream of said occlusion member.

Regarding claim 8, The catheter apparatus of claim 7, further comprising a second perfusion lumen within said catheter shaft (between 16 and 16' in figure 8).

Regarding claim 9, The catheter apparatus of claim 1, further comprising a tubular sheath (16 over 16' in fig. 8) fully capable of fit over said expandable conduit when in said collapsed position.

Regarding claim 10, The catheter apparatus of claim 6, wherein said occlusion member is an inflatable occlusion balloon (20 on the second filter, fig. 8).

Regarding claim 12. The catheter apparatus of claim 1, wherein said catheter shaft is positioned internal to said expandable conduit (as shown).

Claims 1-3, 6-10 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Macoviak et al (6254563 or 6139517 based on provisional 60/069490). Macoviak et al discloses a catheter apparatus (fig. 7) for use in a body passage, comprising:

a catheter shaft (232);

an expandable conduit (342, fig.19) defined by a filter mesh material of varying porosity (the mesh is expandable so the pores are varying, the mesh is fibers of radial and annular member which have a tapered hole which get smaller as the mesh gets closer to the catheter 16, additionally members 28 are woven into the mesh also varying the porosity, it is also established on the record by the 132 declaration 12/17/2004 that conical filters figs. 17-19 inherently have varying porosity) mounted on said catheter shaft (232), said expandable conduit having an upstream end and a downstream end, said expandable conduit having a collapsed position in which said expandable conduit is collapsed toward said catheter shaft (see fig. 8) and an

expanded position in which said upstream end of said expandable conduit is open to fluid flow (as shown in fig. 7); and

an upstream sealing member (206 or 204, a balloon) at said upstream end of said expandable conduit for creating a seal between said upstream end of said expandable conduit and an internal wall of the body passage (as shown in fig. 7).

Regarding claim 6, The catheter apparatus of claim 1, further comprising an occlusion member for selectively occluding said expandable conduit (the proximal balloon 206 with the distal filter as shown in fig. 19).

Regarding claim 7, The catheter apparatus of claim 6, further comprising an infusion lumen within said catheter shaft having an infusion port (216) upstream of said occlusion member.

Regarding claim 8, The catheter apparatus of claim 7, further comprising a second perfusion lumen within said catheter shaft (between 230 and 232).

Regarding claim 10, The catheter apparatus of claim 6, wherein said occlusion member is an inflatable occlusion balloon (206, fig. 7).

Regarding claim 9, The catheter apparatus of claim 1, further comprising a tubular sheath (fig. 8) fully capable of fit over said expandable conduit when in said collapsed position.

Regarding claim 12. The catheter apparatus of claim 1, wherein said catheter shaft is positioned internal to said expandable conduit (as shown fig. 7 i.e. within the balloon seal).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Engelson et al (US 6066158)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas J Sweet/
Primary Examiner, Art Unit 3774